

REMARKS

Claims 60 to 64 and 66 to 72 are pending. Claims 60 and 66 have been amended. Claims 63, 64, and 67 have been canceled. All pending claims have been rejected. No new matter is presented. In view of the foregoing amendments and the following remarks, Applicants respectfully request consideration.

Interview with the Examiner

Applicant thanks Examiner Jane Zara for conducting the telephone interview with Applicant's representative on May 14, 2003. The issue of enablement was discussed in the interview. The issue of the term "prevent" was also discussed. In view of the interview applicant has amended the claims and presents the attached arguments in support of the claims.

Sequence Compliance

Applicant has amended the specification to add SEQ ID numbers and has submitted herewith a substitute sequence listing.

Maintained Rejection

The rejection of claims 60-64 and 66-72 under 35 USC 112 first paragraph has been maintained.

As discussed in the interview with the Examiner, Applicant has amended the claims to remove the word “prevention” and to limit the types of lysosomal UCP inhibitors useful in the methods. The lysosomal UCP inhibitors are molecules, including peptides, which interact with lysosomal UCP and inhibit its activity. These types of inhibitors are well described in the specification. For instance, the inhibitors are described on pages 21-29 and 49. Lysosomal targeting motifs are described on pages 42-43.

In view of this description in the specification, one of skill in the art is enabled to use one of these inhibitors to contact a cell, such as a T cell or a neutrophil, and cause regulation of lysosomal pH (claim 60) or treat an infectious disease (claim 66). The specification adequately teaches how to make and use these inhibitor binding molecules.

Additionally, Applicant has submitted a declaration in response to the last office action which demonstrates that 1) UCP inhibitors regulate lysosomal pH, and 2) UCP inhibitors result in the prevention or treatment of infectious diseases. No scientific reason has been provided as to why the *in vitro* and *in vivo* data presented in the declaration is not predictive of the claimed subject matter. The only reason provided is that the findings in the *in vivo* model is “not enabling for the broad scope claimed.” Applicant is entitled to broad claims. Applicant was the first to discover the presence of UCP in the lysosome as well as the physiological significance of lysosomal UCP. Applicant discovered (as described in the specification, i.e., pages 12-13 and 47-51) that modification of lysosomal pH using inhibitors of UCP function results in the promotion of antigen presentation and thus the promotion of an antigen specific immune response and the promotion of respiratory burst, which is useful in treating intracellular pathogens. The processes of antigen presentation and its role in the treatment of infectious disease as well as that of respiratory burst are well known in the art. Applicants discovery of the role of inhibition of lysosomal UCP in these processes as well as the specific inhibitors and

methods for accomplishing this inhibition are described in detail in the specification. The full scope of the claimed invention has been enabled.

If the rejection is based on the potential of prior art to read on broad claims, then it is requested that such a prior art rejection be made.

New Rejection under 35 USC 112

According to the office action, the description provided does not concisely identify members of the genus of lysosomal UCP inhibitors.

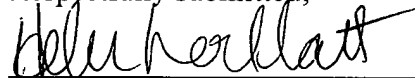
Applicant has amended the claims to specifically list the lysosomal UCP inhibitors as being selected from the group consisting of lysosomal targeted binding peptide and a lysosomal targeted binding molecule. Each of these types of lysosomal UCP inhibitors is defined in detail in the specification. It is believed that the amendment is sufficient to overcome the rejection.

SUMMARY

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

A Request for Three-Month Extension of Time and check in the amount of \$465.00 is enclosed. If there is any further fee due with this response that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,



Helen C. Lockhart, Reg. No. 39,248
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, MA 02210-2211
(617) 720-3500

Docket No. V00139.70059.US
Date: July 14, 2003
X07/14/03